

Response to August 11, 2005, Office Action
Application No. 10/700,239
Page 21

Remarks

Claims 1-25 are pending in the above-identified application. Claims 26-73 and 75-94 are presently withdrawn from consideration. Claim 74 was canceled in a previous paper. In the present Office Action, Claims 1-25 are rejected by the PTO. In this paper, claims 1, 10, and 21 are amended.

Support for claim 1 as amended can be found at least on claim 1 as originally filed; support for "wherein the expression of the polypeptide can occur in the absence of a viral nucleocapsid" can be found at least on page 9, lines 7-10.

Support for claim 10 as amended can be found at least on claim 10 as originally filed; support for "wherein the expression of the polypeptide can occur in the absence of a viral nucleocapsid" can be found at least on page 9, lines 7-10.

Support for claim 21 as amended can be found at least on claim 21 as originally filed; support for "wherein the transcription termination site is an RNA polymerase I transcription termination site" can be found at least on paragraph 34 on pages 18-19.

Responses to the PTO's actions are as follows.

The Detailed Actions included a notice of change of examiner. Applicant notes that correspondence regarding this application is to be sent to Examiner Salvoza in Group Art Unit 1648.

In the Detailed Actions, the PTO maintains the restriction requirement issued January 26, 2005, noting the election of Group I, claims 1-19 and 21-25, and Applicant's request to add

Response to August 11, 2005, Office Action
Application No. 10/700,239
Page 22

claim 20 to the Group. Because the PTO states that "Claims 1-25 are pending and under consideration," Applicant assumes that claim 20 has been added back to Group I.

Oath/Declaration

Applicant requests reconsideration of the statement of defective oath or declaration, because a properly executed oath or declaration was, in fact, submitted to the PTO.

In the present paper, the PTO states that an oath or declaration filed is defective because it lacks proper signatures, in view of refileing of a revised declaration/power of attorney on November 13, 2003. However, our records indicate that a revised declaration/power of attorney with proper signatures was filed with the PTO on November 21, 2003, the receipt of which was acknowledged by the PTO by return postcard dated November 21, 2003 (copy of Request for filing Substitute Declaration, Declaration and Power of Attorney, and return postcard attached hereto). Accordingly, Applicant, therefore, requests reconsideration and withdrawal of this request for new oath or declaration.

Specification

The PTO states that the Application number is missing from the first page of the Application and requests correction. However, Applicant is unaware of any law, rule, or regulation requiring inclusion of an Application number on a first page. Applicant, therefore, requests reconsideration and withdrawal of this request.

Response to August 11, 2005, Office Action
Application No. 10/700,239
Page 23

The PTO states that the Application number is missing from the abstract and requests correction. However, Applicant is unaware of any law, rule, or regulation requiring inclusion of an Application number on an abstract. Applicant, therefore, requests reconsideration and withdrawal of this request.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 21 was rejected under 35 U.S.C. § 112, second paragraph for lacking an antecedent basis for recitation of "the transcription termination signal." Applicant requests reconsideration and withdrawal of this rejection as claim 21 has been amended to recite a "transcription termination site," thus having proper antecedent basis in claim 11, from which it depends.

Rejection under 35 U.S.C. § 102

In the present Office Action, the PTO rejects claims 10-16, 19-23, and 25 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,270,958 to Olivo et al. ("Olivo"). Applicant respectfully traverses this rejection.

To anticipate a claim, a reference must teach, expressly or inherently, each and every element of the claim. MPEP § 2131.

In the present office action, the PTO cites claim 11 of Olivo for teaching a method of detecting a negative strand RNA virus. This method comprises incubating a genetically engineered cell with a sample, wherein the cell contains a polynucleotide encoding a DNA-dependent RNA polymerase; a cDNA comprising a minigenome and a miniantigenome of the

Response to August 11, 2005, Office Action
Application No. 10/700,239
Page 24

negative-strand RNA virus operably linked to a promoter for the DNA-dependent RNA polymerase, wherein the antigenome comprises a reporter gene; and "one or more nucleotide sequences encoding each of the nucleocapsid proteins of the negative-strand RNA virus which are necessary and sufficient for replication of minigenome RNA or miniantigenome RNA synthesized by the DNA-dependent RNA polymerase."

In contrast, claim 10 of the present application recites, *inter alia*, that expression of the reporter protein can occur in the absence of a viral nucleocapsid protein. Because claim 11 of Olivo requires the encoding and expression of nucleocapsid proteins, it does not anticipate claim 10 of the present application. Accordingly, applicant requests reconsideration and withdrawal of the rejection of claim 10 under 35 U.S.C. § 102.

Applicant requests reconsideration and withdrawal of the rejections of claims 11-16, 19-23, and 25 because a claim in dependent form incorporates all the elements of the claim to which it refers. 35 U.S.C § 112, fourth paragraph. Because claim 10 is not anticipated by Olivo for the reasons presented above, none of claims 11-16, 19-23, and 25 are anticipated by Olivo.

Applicant, therefore, requests reconsideration and withdrawal of the rejections of these claims under 35 U.S.C. § 102.

Rejections under 35 U.S.C. § 103

In the present Office Action, the PTO rejects claims 1-9, 17, 18 and 24 as obvious under 35 U.S.C. § 103(a). Applicant requests reconsideration and withdrawal of the rejections, because the PTO has not established a *prima facie* case of obviousness for any of the claims.

Response to August 11, 2005, Office Action
Application No. 10/700,239
Page 25

In order to establish a *prima facie* case of obviousness of a claim, the PTO must show that a) a cited reference, or combination of references, teaches or suggests each and every claim element; b) there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; and c) there is a reasonable expectation of success. MPEP § 2142.

In the present Office Action, the PTO rejects claims 1, 3, 6, 7, 8, and 9 for obviousness in view of U.S. 6,270,958 to Olivo et al. ("Olivo"). The PTO's rejection rests on its assertion that "it would be *prima facie* obvious to one of ordinary skill in the art when using either RNA or DNA as a construct." However, the PTO has not demonstrated any of the three requirements for establishing *prima facie* obvious: the PTO has not shown that Olivo teaches or suggests each and every claim element; the PTO has not shown that Olivo presents any suggestion or motivation to modify the reference; and the PTO not established that the teachings of Olivo present a reasonable expectation of success for detection of a segmented negative strand RNA virus using a genetically engineered vertebrate cell comprising a recombinant RNA molecule that comprises a reporter gene encoding a polypeptide, in which expression of the polypeptide can occur in the absence of a viral nucleocapsid protein. Accordingly, the PTO has not established *prima facie* obviousness for claims 1, 3, 6, 7, 8, and 9 in view of Olivo.

In the present Office Action, the PTO rejects claims 2, 17, 18 and 24 as obvious over the '958 patent and Neumann *et al* ("Neumann"). However, the PTO has not shown *prima facie* obviousness for these claims, because neither Olivo nor Neumann, singly or in combination,

Response to August 11, 2005, Office Action
Application No. 10/700,239
Page 26

teach or suggest each and every claim element of any of claims 2, 17, 18 or 24. Claim 2, by virtue of its dependence from claim 1, and claims 17, 18 and 24, by virtue of their dependence from claim 10, recite methods for detecting the presence, absence, or quantity of a segmented negative strand virus comprising, *inter alia*, contacting a biological specimen with a genetically engineered vertebrate cell comprising a recombinant RNA (for claim 2) or DNA (for claims 17, 18 and 24) molecule that comprises a reporter gene encoding a polypeptide, in which expression of the polypeptide depends upon the presence in the cell of an RNA-dependent RNA polymerase of the virus and wherein the expression of the polypeptide can occur in the absence of a viral nucleocapsid protein. In contrast, as discussed *supra*, Olivo explicitly requires the encoding and expression of viral nucleocapsid proteins for expression of a reporter gene polypeptide. Neumann is directed to an RNA polymerase I transcription system for influenza viral hemagglutinin cDNA flanked by an rDNA promoter. Neumann does not teach a method for detecting the presence, absence, or quantity of a segmented negative strand virus. Furthermore, Neumann does not teach a method that includes contacting a biological specimen with a genetically engineered vertebrate cell comprising a recombinant RNA (or DNA) molecule that comprises a reporter gene encoding a polypeptide. Accordingly, the PTO has not shown that Olivo and Neumann, either singly or in combination, teach or suggest a method for detection of a segmented negative strand RNA virus using a genetically engineered vertebrate cell comprising a recombinant RNA (or DNA) molecule that comprises a reporter gene encoding a polypeptide in which expression of a reporter polypeptide depends upon the presence in the cell of an RNA-dependent RNA polymerase of the virus and can occur in the absence of a viral nucleocapsid

Response to August 11, 2005, Office Action
Application No. 10/700,239
Page 27

protein. Therefore, Olivo and Neumann, considered either singly or in combination, do not establish *prima facie* obviousness for any of claims 2, 17, 18 or 24.

In the present Office Action, the PTO rejects claims 4 and 5 as obvious over Olivo and Fodor et al. ("Fodor"). However, the PTO has not shown *prima facie* obviousness for these claims, because neither Olivo nor Fodor, viewed singly or in combination, teach or suggest each and every claim element of either claim 4 or claim 5. These claims, by virtue of their dependence from claim 1, recite methods for detecting the presence, absence, or quantity of a segmented negative strand virus comprising, *inter alia*, contacting a biological specimen with a genetically engineered vertebrate cell in which expression of a reporter polypeptide depends upon the presence in the cell of a viral RNA-dependent RNA polymerase and can occur in the absence of a viral nucleocapsid protein. In contrast, neither Olivo nor Fodor, alone or in combination, teach viral detection which involves the expression of a reporter gene polypeptide that depends upon the presence in the cell of a viral RNA-dependent RNA polymerase and can occur in the absence of a viral nucleocapsid protein. As discussed *supra*, Olivo explicitly requires the encoding and expression of viral nucleocapsid proteins for expression of a reporter gene polypeptide. Fodor teaches rescue of influenza A virus by transfection of Vero cells with 12 plasmids. These plasmids include, *inter alia*, a plasmid which expresses nucleocapsid protein from an adenovirus type 2 major late promoter. Accordingly, both Olivo and Fodor teach methods which require expression of influenza nucleocapsid protein; the PTO has not shown that Olivo or Fodor, either singly or in combination, teach detection of influenza virus using a genetically engineered vertebrate cell in which expression of a reporter polypeptide depends

upon the presence in the cell of a viral RNA-dependent RNA polymerase and can occur in the absence of a viral nucleocapsid protein. The PTO, therefore, has not established *prima facie* obviousness for either claim 4 or claim 5.

Accordingly, because the PTO has not shown that the teachings of the references cited by the PTO, individually or in combination, establish *prima facie* obviousness for any of claims 1-9, 17, 18 and 24 in the present application, Applicant respectfully requests withdrawal of these rejections for obviousness under 35 USC § 103.

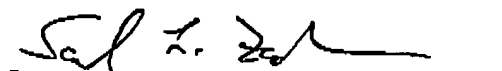
Conclusion

As it is believed the application is in a condition for allowance, Applicant requests prompt and favorable action.

Applicant requests that the Examiner contact the undersigned attorney by telephone if a discussion would be of benefit toward gaining a rapid allowance of the claims.

Dated: Nov 7, 2005

Respectfully submitted,



Saul L. Jackson, Ph.D.
Reg. No. 52,391
Customer No. 26263
Tel: 314.259.5802
e-mail: szackson@sonnenschein.com